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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,273	03/01/2002	John R. Gordon	4616-62430	3115

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,273	GORDON ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-86* is/are pending in the application.

4a) Of the above claim(s) *84-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-79 have been canceled previously. Amended claims 80-83 (6/2/2005) are under consideration.

2. Receipt of applicant's arguments and amendments filed on 6/2/2005 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 6/2/2005:

(i) the rejection of claims 87-90 under 35 USC 101.

4. Applicant's arguments filed on 6/2/2005 have been fully considered and were persuasive in part. The issues remaining are restated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim rejections-35 USC § 112, first paragraph

6. Claims 80-83 are rejected under 35 U.S.C. 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 3-4 of the previous Office action (1/31/2005).

Applicants argue that "substantially equivalent" at lines 8-22 of paragraph 0005 of the application is defined as "the novel antagonist proteins also include those that are substantially equivalent (that is, those that contain amino acid substitutions, additions and deletions that do not delete the CXCR1 and CXCR2 binding functions). To a wild-type bovine CXCL8 protein...and also bear a truncation of the first two amino acid residues along with substitutions of Lys11 with Arg and Gly31 with Pro". However, contrary to applicants' arguments, the issue here is that the specification states that "substantially equivalent" **includes amino acid substitutions, additions**

and deletions that do not delete the CXCR1 and CXCR2 binding functions. Applicants are only enabled for: (1) an isolated protein consisting of an amino acid sequence set forth in SEQ ID NO:1; (2) an isolated protein of amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 30 of SEQ ID NO:1 is Gly instead of Pro; (3) an isolated protein of amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 10 of SEQ ID NO:1 is Ser instead of Thr; and (4) an isolated protein of amino acid sequence set forth in SEQ ID NO:1 wherein amino acid 11 of SEQ ID NO:1 is Phe instead of His, and the specification does not reasonably provide enablement for an antagonist comprising an amino acid sequence "substantially equivalent" to the amino acid sequence set forth in SEQ ID NO:1. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This position is consistent with the decisions in In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) and Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., 13 USPQ2d, 1737 (1990), and In re Wands, 8USPQ2d, 1400 (CAFC 1988) (which has been cited by Applicants. If Applicants will kindly review page 1404 of In re Wands, they will find that the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims. Applicants arguments that the standard is that of mutating a subject protein and testing to see if it retains the desired biological activity (in this case, for the ability to bind

CXCR1 and CXCR2) is a position that has been routinely dismissed by the courts, as shown by the decisions cited above.

Further, In re Wands determined that the repetition of work which was disclosed in a patent application as producing a composition containing an antibody, which is a naturally-occurring compound, did not constitute undue experimentation even if the antibody produced thereby was not identical to those that were disclosed in that application. The instant claims are not limited to naturally-occurring compounds and the instant specification does not provide a description of a repeatable process of producing a ELR-CXC chemokine antagonist whose amino acid sequence deviates from the ones recited in claims 81-83. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial inventive contribution on the part of a practitioner which would involve the determination of those amino acid residues of the ELR-CXC chemokine antagonist which are required for functional and structural integrity of those proteins. It is this additional characterization of the disclosed protein that is required in order to obtain the functional and structural data needed to permit one to produce an antagonist protein which meets both the structural and functional requirements of the instant claims that constitutes undue experimentation.

Furthermore, Applicant is encouraged to review the discussion of 35 U.S.C. § 112, first paragraph, in a recent CAFC decision, Genentech, Inc. v. Novo. Nordisk, 42 USPQ2d, 100 (CAFC 1997), in which the decisions in In re Fisher, Amgen Inc. V. Chugai Pharmaceuticals Co. Ltd., and In re Wands were considered as the controlling precedents in determining enablement issues where protein and recombinant DNA issues are concerned. These decisions have been

relied upon in the instant rejection and by the Court because they show that the judicial interpretation of the first paragraph of 35 U.S.C. § 112 requires that the breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work than not, without actually making and testing them, then the instant application does not support the breadth of the claims.

Applicants argue that an alignment has been provided to predict by comparison with bovine CXCL8 with other CXCL8 sequences, which amino substitutions, additions and deletions will be tolerated. However, contrary to Applicants arguments, with respect to the rejection of claim 80, the teachings of the present application, especially when taken together with the knowledge of one of ordinary skill in the pertinent art, does not provide an enabling disclosure for present claim 80. There is not adequate guidance as to the nature of the analogues or variants that may be constructed, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation. Furthermore, claim 80 does not indicate the number of substitutions, additions or deletions i.e. there is no upper limit to the amount of substitutions additions or deletions. Therefore Applicants have not presented enablement commensurate in scope with the claims.

Claim rejections-35 USC § 112, second paragraph

7. Claims 80-83 are rejected under 35 U.S.C. 112, second paragraph.

This rejection is maintained for reasons of record set forth at pages 4-5 of the previous Office action (1/31/2005).

Applicants argue that a definition for "substantially equivalent" has been provided at lines 8-22 of paragraph 0005 of the specification. However, contrary to Applicants' arguments, the metes and bounds of the claim are unclear because as argued above, by the recitation of "substantially equivalent" there is no upper limit on the number of additions, substitutions and deletions that can be made to SEQ ID NO:1. Therefore, claim 80 remains vague and indefinite and claims 81-83 are rejected insofar as they depend on claim 80 for its limitations.

Claim Rejections - 35 USC § 102

8. Claim 80 is rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/00601 (1997).

This rejection is maintained for reasons of record set forth at page 5 of the previous Office action (1/31/2005).

Applicants argue that their previous arguments have obviated this 35 U.S.C. 102(b) rejection. However, contrary to Applicants' arguments, the recitation of "substantially equivalent" in claim 80 is unclear and necessitates that this rejection be maintained since the reference teaches an IL-8 mutant substantially equivalent to the amino acid sequence of SEQ ID NO:1.

Conclusion

No claim is allowed.

Claims 80-83 are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
June 8, 2005